DOCKET NO. AH0948Q



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

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| In re Application of: Shih *et al* | ) | Examiner: N. Levy |
| | ) | Group Art Unit: 1616 |
| Serial No.: 09/431,519 | ) | |
| Filed: November 1, 1999 | ) | Atty. Docket No.: AH0948Q |

For: IMPROVED GROWTH STIMULANT COMPOSITIONS

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

APPEAL BRIEF UNDER 37 C.F.R. 1.192

This appeal is taken from the decision of the Primary Examiner mailed on October 23, 2002, in which claims of the subject application were finally rejected. Applicants filed an Amendment after Final Rejection on February 2, 2001. Applicants filed a Notice of Appeal with Board of Patent Appeals and Interferences on December 10, 2002. Reversal of the Final Rejection and allowance of all the appealed claims in the case are respectfully solicited.

This Brief is being filed in triplicate. Please charge any applicable fees or credit overpayments to Deposit Account No. 19-0365.

1. Real Party in Interest

The real party in interest in this appeal is Schering Corporation, assignee of the subject patent application by virtue of an assignment executed by the inventors.

2. Related Appeals and Interferences

There are no related appeals or interferences, which will affect or be affected by a decision in this appeal.

3. Status of Claims

The application was originally filed with Claims 1-42. Claims 21-42 were withdrawn in response to the Restriction Requirement of March 17, 2000. An January 2, 2001 amendment to Claim 1 was made in a response to the Office Action which issued on July 14, 2000. No amendment was made in the July 9, 2001 response to the March 29, 2001 Office Action. A Final Office Action was issued on October 9, 2001. Applicants filed a CPA application on February 11, 2002 without amending the claims. Amendments to Claims 1, 11 and 12 were made in a June 18, 2002 response to an Office Action which issued on March 18, 2002. A Final Rejection issued on October 23, 2002 to which Applicants are filing this Appeal Brief. An Amendment to Claim 1 is being filed concurrently with this Appeal Brief to adopt the Examiner's suggestion made on the October 23, 2002 Office Action and to remove issues from appeal. Accordingly, Claims 1-20 after entering the Amendment of February 14, 2003, remain in the application and are subject of this Appeal.

4. Status of Amendments

The Examiner withdrew claims 21-42 from further consideration as being drawn to a non-elected invention. Applicants' Amendment to Claim 1 on January 2, 2001 was acknowledged by the Examiner in the Office Action which issued on March 29, 2001. Applicants' amendment to Claims 1 and 11 on June 18, 2002,

was acknowledged by the Examiner in the Office Action which issued on October 23, 2002. Accordingly, Applicants believe the amendments to claims 1, 11 and 12 were entered.

5. Summary of the Invention

The claimed invention teaches and claims an anabolic implant dual formulation composition comprising: (i) an immediate-release first formulation consisting essentially of an anabolic agent, and (ii) a controlled-release second formulation comprising an anabolic agent and a controlled-release agent, wherein said immediate-release formulation and said controlled-release formulation cooperate to effect stimulation, and wherein said anabolic agent, which may be the same or different in each formulation, is selected from the group consisting of zeranol, estradiol, testosterone, salbutamol, progesterone, trenbolone acetate, and combinations thereof. See claim 1 as well as "Summary of the Invention" and "Description of the Invention." The invention is aimed at a dual formulation composition useful for stimulating increased growth in cattle, wherein one formulation is an immediate-release formution, and the second formulation is a controlled-release formulation. The controlled-release formulation of the claimed invention is a polymer matrix which is biocompatible. See page 7, lines 11-14. Appellants amended claim 1 to require that the immediate-release formulation consists essentially of an anabolic agent selected from the group consisting of zeranol, estradiol, testosterone, salbutamol, progesterone, trenbolone acetate, and combinations thereof. Therefore, the immediate-release formulation cannot contain a controlled-release agent, a polymer matrix, or any other substance which would materially affect the basic and novel characteristics of the immediate-release formulation. Inventive dual formulations useful in stimulating growth in cattle are listed on page 15, lines 11-22 as formulations G-J. The appealed claims all demonstrate the desired weight-gain effect of the instant anabolic dual-formulation composition on cattle. As shown by the Examples and Test Results disclosed in the specification.

6. Issues

1 **Rejection under 35 USC § 102(b), or, in the alternative, under 35 USC § 103(a).** Whether the originally filed claims 1-42 or, in the alternative, the amended claims 1-20, are anticipated under 35 USC §102(b), or, in the alternative, are obvious under 35 USC §103(a) by *Gresser et al*? Is the claimed composition clearly anticipated or obvious to one skilled in the art?

2 **Rejection under 35 USC § 102(b).** Whether the originally filed claims 1-42 or, in the alternative, the amended claims 1-20, are anticipated under 35 USC §102(b) by *Lewis*? Is the claimed composition clearly anticipated to one skilled in the art?

3 **Rejection under 35 USC § 103(a).** Whether the originally filed claims 1-42 or, in the alternative, the amended claims 1-20, are rendered obvious under 35 USC §103 by (a) *Lewis* and (b) *Lee et al*? Is the claimed composition clearly obvious to one skilled in the art?

7. Grouping of Claims

It is submitted that the patentability issues for the originally filed claims 1-42 or, in the alternative, the amended claims 1-20 are similar. The claims therefore are considered to stand or fall together in either case.

8. Argument

**1. Rejection under 35 USC §102(b), or, in the alternative, 35 USC §103(a)**

**The Examiner's View of Anticipation and Obviousness is erroneous in the instant case**

Anticipation

On pages 2-3 of the Final Rejection dated October 23, 2002, the Examiner

contends that the *Gresser* reference demonstrates a formulation that consists essentially of an anabolic agent selected from the group consisting of zeranol, estradiol, testosterone, salbutamol, progesterone, trenbolone acetate, and combinations thereof. Appellants believe that the Examiner's rejections are based on generalized opinions rather than *prima facie* evidentiary statements that contain reasonings to support his statements. In fact, the Examiner fails to cite even a single line from either reference to support his conclusions. Appellants further believe that the rejections are based on flawed reading or interpretation of the cited references and, therefore, do not establish anticipation or obviousness as required by the law.

*Gresser* discloses a biodegradable polymeric multiphasic release system of one or more bursting units **wherein each bursting unit includes a bioactive agent encapsulated in a biodegradable, biocompatible polymeric membrane**. See Page 4, lines 23-26.

In contrast, the claimed invention, as stated above, is a **dual formulation composition** comprising an immediate-release first formulation consisting essentially of an anabolic agent and a controlled-release second formulation comprising an anabolic agent and a controlled-release agent formulation wherein the anabolic agent, which may be the same or different in each formulation, is selected from the group consisting of zeranol, estradiol, testosterone, salbutamol, progesterone, trenbolone acetate, and combinations thereof.

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s) of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). A significant difference between the controlled release formulation and the immediate-release formulation of the claimed invention is that the controlled-release formulation has a polymer matrix to control the release of the anabolic agent, and the immediate-release formulation does not have a polymer matrix to control the release of the anabolic agent. (See page 7 of specification). Because the immediate-release first formulation consists essentially of an anabolic agent, it cannot contain the polymer matrix of the controlled-release formulation in the claimed invention. To include the polymer matrix of the controlled-release formulation in the immediate-release formulation of the claimed invention

would materially affect the basic and novel characteristics of the immediate-release formulation, and therefore, materially affect the basic and novel characteristics of the anabolic implant dual formulation composition of the claimed invention.

Similarly, because the immediate-release first formulation of the claimed invention consists essentially of an anabolic agent, it cannot contain a biodegradable, biocompatible polymeric membrane as *Gresser* would require.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co.* 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Since the teachings of *Gresser* would require one skilled in the art to include a biodegradable, biocompatible polymeric membrane in the immediate-release formulation of the claimed invention, *Gresser* would require one skilled in the art to materially affect the basic and novel characteristics of the immediate-release formulation, and thereby materially affect the basic and novel characteristics of the anabolic implant dual formulation composition of the claimed invention. Thus, *Gresser* does not enable the invention.

Furthermore, *Gresser* does not disclose or suggest using an anabolic agent selected from the group consisting of zeranol, estradiol, testosterone, salbutamol, progesterone, trenbolone acetate, and combinations thereof, which is claimed in the claimed invention. Accordingly, the claimed invention is not anticipated by *Gresser*.

Obviousness

To establish a *prima facie* case of obviousness three must be some suggestion or motivation, either in the reference themselves or knowledge known to the skilled artisan, to modify the reference or combine the reference teachings. See MPEP 2143. The mere fact that references can be combined does not render the resultant combination obvious unless the prior art also suggests the desirability of doing so. See *In Re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). Another requirement for establishing a *prima facie* case of obviousness of a claimed invention is that all the claim limitations must be taught or suggested by the prior art.

*In Re Royka*, 490 F.2d 981, 180 USPQ 580 (CPPA 1974).

As stated above, each and every element of the claimed invention is not disclosed in the *Gresser* reference. Furthermore, there is no suggestion or motivation in *Gresser,* and it is not known to one skilled in the art, to modify the invention disclosed in Gresser such that the skilled artisan would combine an immediate-release formulation with a controlled-release formulation as disclosed in the claimed invention. Accordingly, the Examiner has not met his burden of factually supporting a *prima facie* case of obviousness, and the claimed invention in neither anticipated nor rendered obvious by the *Gresser* reference.

Appellants strongly believe that the claimed invention is substantially and patentably distinct from *Gresser.* Appellants respectfully assert that there is simply no teaching in *Gresser* to motivate one skilled in the art to achieve the claimed invention, no matter how broadly one reads into *Gresser.* The claimed invention cannot be deemed unpatentable merely because, in a hindsight attempt to reconstruct the invention, one can find some of its pieces or elements in the art; it must be shown that the invention as a whole was obvious at the time the invention was made without knowledge of the claimed invention, 35 U.S.C. 103. Appellants believe that the Examiner has not met his burden of proving how a reading of the *Gresser* reference makes the claimed invention anticipated or obvious. Nor has the Examiner presented a convincing line of reasoning as to why a skilled artisan would even be motivated to make the immediate-release formulation of the claimed invention, or to use the specific anabolic agents listed in the Markush group in the claimed invention.

In the Final Rejection dated October 23, 2002, the Examiner states that *Gresser* demonstrates a formulation consisting essentially of an anabolic agent in the absence of evidence to the contrary. The Examiner has used that argument to reject the amended claims. The Examiner is indulging in conjecture rather than providing any objective evidence for such a statement. This is a rejection based on anticipation, or, alternatively, obviousness and the Examiner has not cited any teaching to motivate the skilled artisan to come up with the dual formulation composition of the claimed invention other than stating without any evidence that *Gresser* demonstrates a formulation consisting essentially of an anabolic agent.

Thus, it is believed that the instant invention, either based on the originally filed claims, or at least based on the amended claims, is novel and non-obvious over *Gresser*.

**2. Rejection under 35 USC §102(b)**

**The Examiner's View of Anticipation is erroneous in the instant case**

On page 3 of the Final Rejection dated October 23, 2002, the Examiner contends that the *Lewis* reference anticipates the claimed invention because the claimed invention does not preclude non-active materials. Appellants believe that this rejection is based on flawed reading or interpretation of the cited references and, therefore, do not establish anticipation as required by the law.

*Lewis* discloses long-acting biodegradable microparticles which contain a growth promoter. See Column 3, lines 25-32. The microparticles are composed of a polymeric matrix material which must be biocompatible and biodegradable. See Column 3, lines 41-43, and Column 4, lines 3-5.

In contrast, the claimed invention, as stated above, is a dual formulation composition comprising an immediate-release first formulation consisting essentially of an anabolic agent and a controlled-release second formulation comprising an anabolic agent and a controlled-release agent formulation wherein the anabolic agent, which may be the same or different in each formulation, is selected from the group consisting of zeranol, estradiol, testosterone, salbutamol, progesterone, trenbolone acetate, and combinations thereof.

Because the immediate-release first formulation of the claimed invention consists essentially of an anabolic agent, it cannot contain a biodegradable, biocompatible polymeric material as the teachings of *Lewis* would require one skilled in the art to do. To include the biodegradable, biocompatible polymeric material in the immediate-release formulation of the claimed invention, as *Lewis* would require one skilled in the art to do, would materially affect the basic and novel characteristics of the immediate-release formulation, and therefore, materially affect the basic and novel characteristics of the anabolic implant dual formulation composition of the claimed invention. Accordingly, each and every element of the claimed invention is not disclosed in the *Lewis* reference, and therefore, *Lewis* does not anticipate the claims of the present invention.

Appellants strongly believe that the claimed invention is substantially and patentably distinct from *Lewis*. Appellants respectfully assert that there is simply no teaching in *Lewis* to motivate one skilled in the art to achieve the claimed invention, no matter how broadly one reads into *Lewis*. Appellants believe that the Examiner has not met his burden of proving how a reading of the *Lewis* reference makes the claimed invention anticipated. Nor has the Examiner presented a convincing line of reasoning as to why a skilled artisan would even be motivated to make the immediate-release formulation of the claimed invention.

In the Final Rejection dated October 23, 2002, the Examiner states that the claim language does not preclude adjuvant and other non-active materials. The Examiner has used that argument to reject the amended claims. The Examiner is indulging in conjecture rather than providing any objective evidence how each and every element of the claimed invention is disclosed or suggested in the *Lewis* reference. This is a rejection based on anticipation and the Examiner has not cited any teaching to motivate the skilled artisan to come up with dual formulation composition of the claimed invention other than stating without any evidence that the claim language does not preclude adjuvant and other non active materials.

Thus, it is believed that the instant invention, either based on the originally filed claims, or at least based on the amended claims, is novel over *Lewis*.

**3. Rejection under 35 USC §103(a)**

**The Examiner's View of Obviousness is erroneous in the instant case**

On page 3 of the Final Rejection dated October 23, 2002, the Examiner contends that the *Lewis* and *Lee* references anticipates the claimed invention because the first formulation of the claimed invention does not preclude non-active material. Appellants believe that the rejections are based on flawed reading or interpretation of the cited references and, therefore, do not establish anticipation as required by the law.

As discussed above, *Lewis* (the primary reference) does not suggest or discloses the dual formulation of the claimed invention. *Lee* (the secondary reference) discloses coating formulations for coating sustained-release drug implants. See Column 6, lines 25-26. The coating formulations of *Lee* are capable

of forming a porous film over a biologically active agent at a constant rate over a prolonged period of time. See Column 6, lines 26-29.

In contrast, the claimed invention, as stated above, is a dual formulation composition comprising an immediate-release first formulation consisting essentially of an anabolic agent and a controlled-release second formulation comprising an anabolic agent and a controlled-release agent formulation wherein the anabolic agent, which may be the same or different in each formulation, is selected from the group consisting of zeranol, estradiol, testosterone, salbutamol, progesterone, trenbolone acetate, and combinations thereof.

*Lee* does nothing to correct the deficiencies of *Lewis*. Because the immediate-release first formulation of the claimed invention consists essentially of an anabolic agent, it cannot contain the formulation disclosed in *Lee*. The teachings of *Lee* would require one skilled in the art to include a formulation capable of forming a porous film over a biologically active agent at a constant rate over a prolonged period of time in the immediate-release formulation of the claimed invention. Therefore, the teachings of *Lee* would require one skilled in the art to materially affect the basic and novel characteristics of the immediate-release formulation, and thereby materially affect the basic and novel characteristics of the anabolic implant dual formulation composition of the claimed invention. The *Lee* and *Lewis* are both deficient in respect to the immediate-release formulation.

Appellants respectfully assert that there is simply no teaching in the cited references to motivate one skilled in the art to achieve the claimed invention, no matter how broadly one reads into the two references. The claimed invention cannot be deemed unpatentable merely because, in a hindsight attempt to reconstruct the invention, one can find some of its pieces or elements in the art; it must be shown that the invention as a whole was obvious at the time the claimed invention was made without knowledge of the claimed invention, 35 U.S.C. 103. Appellants believe that the Examiner has not met his burden of proving how a reading of the cited references makes the claimed invention obvious. Nor has the Examiner presented a convincing line of reasoning as to why the skilled artisan would even be motivated to combine the two references, given the emphasis on the immediate-release formulation in the claimed invention. Accordingly, the Examiner has not met his

burden of factually supporting a *prima facie* case of obviousness, and the claimed invention in not rendered obvious by the *Lee* and *Lewis* references either alone, or in combination.

On page 3 of the Final Rejection dated October 23, 2002, the Examiner states that the absence of "consisting of" in the first immediate-release formulation is seen as inclusive of non-active components. The Examiner has used that argument to reject the amended claims. The Examiner's reasoning is flawed since the "consisting of" language in the claimed invention precludes one skilled in the art to use the teachings of *Lee* and *Lewis* to make the claimed invention. As stated above, the teachings of *Lee* and *Lewis* each would require one skilled in the art to materially affect the *basic* and *novel* characteristics of the claimed invention. The Examiner is indulging in conjecture rather than providing any objective evidence how each and every element of the claimed invention is disclosed or suggested in the *Lewis* and *Lee* references, either alone, or in combination. This is a rejection based on obviousness and the Examiner has not cited any teaching to motivate the skilled artisan to come up with dual formulation composition of the claimed invention other than stating without any evidence that the absence of "consisting of" in the first immediate-release formulation is seen as inclusive of non-active components. Thus, it is believed that the instant invention, either based on the originally filed claims, or at least based on the amended claims, is patentable over *Lee* and *Lewis.*

In the absence of any reasonable basis to make out a rejection based on anticipation, or, in the alternative, a *prima facie* case for obviousness, reversal of the improper final rejection of appellant's originally filed claims 1-42 or, in the alternative, the amended claims 1-21 is appropriate, and such action is respectfully solicited. Both the originally filed claims 1-42 and the amended claims 1-20 are presented in the Appendix as Paragraphs 9 and 10 respectively.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that the foregoing correspondence entitled APPEAL BRIEF UNDER 37 C.F.R. 1.192 is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to Assistant Commissioner of Patents, Washington, D.C. 20231 on February 14, 2003.

Robert L. Bernstein

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Registration No. 46,020

2/14/03

Date of Signature

9. APPENDIX - CLAIMS ON APPEAL (ORIGINALLY FILED CLAIMS)

CLAIMS

What is claimed is:

1. An anabolic implant composition for stimulating increased rate of growth, greater amount of growth and greater feed efficiency in cattle, said composition comprising: (i) an immediate-release formulation comprising an anabolic agent, and (ii) a controlled-release formulation comprising an anabolic agent and a controlled-release agent, wherein said immediate-release formulation and said controlled-release formulation cooperate to effect said stimulation.

2. The implant composition of claim 1, wherein said immediate-release formulation and said controlled-release formulation are present respectively in a weight ratio range 1:2 to 1:25 in said composition.

3. The implant composition of claim 1, wherein said immediate-release formulation and said controlled-release formulation are present respectively in a weight ratio range 1:2 to 1:10 in said composition.

4. The implant composition of claim 1, wherein said immediate-release formulation and said controlled-release formulation are present respectively in a weight ratio range 1:3 to 1:8 in said composition.

5. The implant composition of claim 1, wherein said composition is subcutaneously injectable in said cattle.

6. The implant composition of claim 1, wherein said immediate-release formulation and said controlled-release formulation contain the same anabolic agent.

7. The implant composition of claim 1, wherein said immediate-release formulation and said controlled-release formulation contain different anabolic agents.

8. The implant composition of claim 1, wherein said anabolic agent is selected from the group consisting of zeranol, estradiol, estradiol benzoate, trenbolone, trenbolone acetate, somatotrophin, testosterone, testosterone propionate, salbutamol, progesterone, and combinations, salts and derivatives thereof.

9. The implant composition of claim 8, wherein said anabolic agent is zeranol.

10. The implant composition of claim 8, wherein said anabolic agent is trenbolone

acetate.

11. The implant composition of claim 9, wherein said zeranol is the anabolic agent in both said immediate-release formulation and said controlled-release formulation and comprises from about 50 wt.% to about 95 wt.% of said composition based on a total weight percentage basis.

12. The implant composition of claim 9, wherein said zeranol is the anabolic agent in both said immediate-release formulation and said controlled-release formulation and comprises from about 60 wt.% to about 80 wt % of said composition.

13. The implant composition of claim 1, wherein said immediate-release formulation additionally contains a diluent.

14. The implant composition of claim 13, wherein said diluent is selected from the group consisting of lactose, mannitol, sorbitol, sucrose, dextrose, starches, hydrolyzed starches, and combinations thereof.

15. The implant composition of claim 14, wherein said diluent is lactose.

16. The implant composition of claim 1, wherein said controlled-release agent is selected from the group consisting of poly(D,L-lactide-co-glycolide), ethyl cellulose, methyl acrylate-methyl methacrylate copolymer, methyl cellulose, hydroxyethyl cellulose, hydroxypropylmethyl cellulose, sodium carboxymethyl cellulose, and combinations thereof.

17. The implant composition of claim 16, wherein said controlled-release agent is poly(D,L-lactide-co-glycolide).

18. The implant composition of claim 16, wherein said controlled-release agent is ethyl cellulose.

19. The implant composition of claim 1, wherein said controlled-release agent comprises from about 1.0 wt.% to about 8.0 wt.% based on the total weight of said implant composition.

20. The implant composition of claim 1, further comprising a bulking agent, binder, excipient, tabletting agent, colorant and combinations thereof.

21. A method for stimulating increased rate of growth, greater amount of growth and greater feed efficiency in cattle, comprising the administration of an anabolic implant composition to said cattle which composition comprises: (i) an immediate-

release formulation comprising an anabolic agent, and (ii) a controlled-release formulation comprising an anabolic agent and a controlled-release agent, wherein said immediate-release formulation and said controlled-release formulation cooperate to effect said stimulation.

22. The method of claim 21, wherein said immediate-release formulation and said controlled-release formulation are present in a weight ratio 1:25 in said composition.

23. The method of claim 21, wherein said administration comprises subcutaneously injecting said composition into said cattle.

24. The method of claim 21, wherein said immediate-release formulation and said controlled-release formulation contain the same anabolic agent.

25. The method of claim 21, wherein said immediate-release formulation and said controlled-release formulation contain different anabolic agents.

26. The method of claim 21, wherein said anabolic agent is selected from the group consisting of zeranol, estradiol, estradiol benzoate, trenbolone, trenbolone acetate, somatotrophin, testosterone, testosterone propionate, salbutamol, progesterone, and combinations, salts and derivatives thereof.

27. The method of claim 26, wherein said anabolic agent is zeranol.

28. The method of claim 27, wherein said zeranol is the anabolic agent in both said immediate-release formulation and said controlled-release formulation and comprises from about 50 wt.% to about 95 wt.% of said composition.

29. The method of claim 27, wherein zeranol is the anabolic agent in both said immediate-release formulation and said controlled-release formulation and comprises from about 60 wt.% to about 80 wt % of said composition.

30. The method of claim 21, wherein said immediate-release formulation additionally contains a diluent.

31. The method of claim 30, wherein said diluent is selected from the group consisting of lactose, mannitol, sorbitol, sucrose, dextrose, starches, hydrolyzed starches, and combinations thereof.

32. The method of claim 31, wherein said diluent is lactose.

33. The method of claim 21, wherein said controlled-release agent is selected from the group consisting of poly(D,L-lactide-co-glycolide), ethyl cellulose, methyl

acrylate-methyl methacrylate copolymer, methyl cellulose, hydroxyethyl cellulose, hydroxypropylmethyl cellulose, sodium carboxymethyl cellulose, and combinations thereof.

34. The method of claim 33 , wherein said controlled-release agent is poly(D,L-lactide-co-glycolide).

35. The method of claim 33, wherein said controlled-release agent is ethyl cellulose.

36. The method of claim 21, further comprising a bulking agent, binder, tabletting agent, excipient, colorant and combinations thereof.

37. A method for stimulating increased rate of growth, greater amount of growth and greater feed efficiency in an animal, said process comprising:

(a) preparing an immediate-release formulation comprising an anabolic agent, in a first shaped object suitable for loading into a device which device is suitable for administration of said shaped object into the animal;

(b) preparing a controlled-release formulation comprising an anabolic agent and a controlled-release agent, in a second shaped object suitable for loading into said device in step (a), wherein said anabolic agent in step (a) and said anabolic agent in step (b) may be the same or different,

(c) loading said device with said first shaped object and said second shaped object in a ratio such that the total anabolic agent is in the 50-95 weight percent range based on the combined weight of said formulation in step (a) and said formulation in step (b); and

(d) administering said shaped objects into the animal, wherein said immediate-release formulation and said controlled-release formulation cooperate to effect the stimulation.

38. The method of claim 37, wherein said anabolic agent in step 9a) and step (b) is the same and is zeranol.

39. The method of claim 37, wherein said controlled-release agent in step (b) is poly(D,L-lactide-co-glycolide), ethyl cellulose, methyl acrylate-methyl methacrylate copolymer, methyl cellulose, hydroxyethyl cellulose, hydroxypropylmethyl cellulose, sodium carboxymethyl cellulose, and combinations thereof.

40. The method of claim 37, further containing lactose in step (a), step (b) or

both.

41. The method of claim 37, wherein said first shaped object, or said second shaped object, or both is a tablet.

42. The method of claim 37, wherein said first shaped object, said second shaped object, or both is a pellet.

10. ALTERNATE CLAIMS ON APPEAL

CLAIMS REMAINING AFTER AMENDMENT AFTER FINAL REJECTION

1. An anabolic implant dual formulation composition comprising: (i) an immediate-release first formulation comprising consisting essentially of an anabolic agent, and (ii) a controlled-release second formulation comprising an anabolic agent and a controlled-release agent, wherein said immediate-release formulation and said controlled-release formulation cooperate to effect said stimulation, and wherein said anabolic agent, which may be the same or different in each formulation, is selected from the group consisting of zeranol, estradiol, testosterone, salbutamol, progesterone, trenbolone acetate, and combinations thereof.

2. The implant composition of claim 1, wherein said immediate-release formulation and said controlled-release formulation are present respectively in a weight ratio range 1:2 to 1:25 in said composition.

3. The implant composition of claim 1, wherein said immediate-release formulation and said controlled-release formulation are present respectively in a weight ratio range 1:2 to 1:10 in said composition.

4. The implant composition of claim 1, wherein said immediate-release formulation and said controlled-release formulation are present respectively in a weight ratio range 1:3 to 1:8 in said composition.

5. The implant composition of claim 1, wherein said composition is subcutaneously injectable in said cattle.

6. The implant composition of claim 1, wherein said immediate-release formulation and said controlled-release formulation contain the same anabolic agent.

7. The implant composition of claim 1, wherein said immediate-release formulation and said controlled-release formulation contain different anabolic agents.

8. The implant composition of claim 1, wherein said anabolic agent is selected from the group consisting of zeranol, estradiol, estradiol benzoate, trenbolone, trenbolone acetate, somatotrophin, testosterone, testosterone propionate, salbutamol, progesterone, and combinations, salts and derivatives thereof.

9. The implant composition of claim 8, wherein said anabolic agent is zeranol.

10. The implant composition of claim 8, wherein said anabolic agent is trenbolone acetate.

11. The implant composition of claim 9, wherein said zeranol is the anabolic agent in both said immediate-release formulation and said controlled-release formulation and comprises from about 50 wt.% to about 95 wt.% of said composition based on the total weight of said implant composition.

12. The implant composition of claim 9, wherein said zeranol is the anabolic agent in both said immediate-release formulation and said controlled-release formulation and comprises from about 60 wt.% to about 80 wt.% of said composition based on the total weight of said implant composition.

13. The implant composition of claim 1, wherein said immediate-release formulation additionally contains a diluent.

14. The implant composition of claim 13, wherein said diluent is selected from the group consisting of lactose, mannitol, sorbitol, sucrose, dextrose, starches, hydrolyzed starches, and combinations thereof.

15. The implant composition of claim 14, wherein said diluent is lactose.

16. The implant composition of claim 1, wherein said controlled-release agent is selected from the group consisting of poly(D,L-lactide-co-glycolide), ethyl cellulose, methyl acrylate-methyl methacrylate copolymer, methyl cellulose, hydroxyethyl cellulose, hydroxypropylmethyl cellulose, sodium carboxymethyl cellulose, and combinations thereof.

17. The implant composition of claim 16, wherein said controlled-release agent is poly(D,L-lactide-co-glycolide).

18. The implant composition of claim 16, wherein said controlled-release agent is ethyl cellulose.

19. The implant composition of claim 1, wherein said controlled-release agent comprises from about 1.0 wt.% to about 8.0 wt.% based on the total weight of said implant composition.

20. The implant composition of claim 1, further comprising a bulking agent, binder, excipient, tabletting agent, colorant and combinations thereof.